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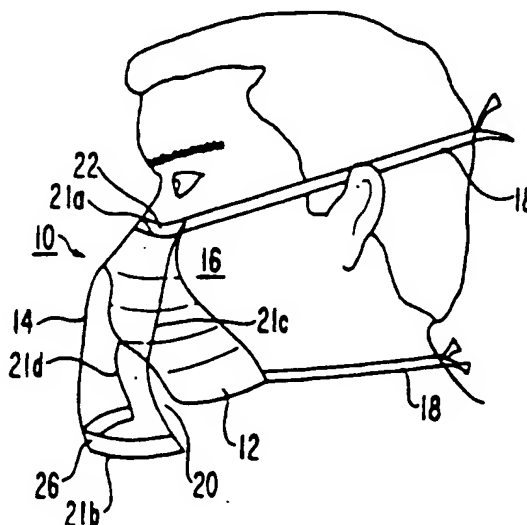
US

(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551
Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).(72) Inventor: BENSON, Hudson, M.; 801 Earleton Road, Havre de
Grace, MD 21078 (US).(74) Agents: JOHNS, David, J. et al.; W.L. Gore & Associates, Inc.,
551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714
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(54) Title: SURGICAL MASK WITH INTEGRAL BAFFLE FOR LIQUID PROOF BARRIER AND/OR LIQUID ABSORPTION



(57) Abstract

The present invention provides an improved face mask including a filtration layer (12) and an attached baffle (14) for protecting the filtration layer of the mask from exposure to liquids. Through one of a variety of disclosed embodiments, the baffle is designed to stand-off from the filtration layer when worn so as to provide an open air space for free flow of respiration. The baffle can be composed of liquid proof material, liquid absorbent material, or a combination of both.

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**SURGICAL MASK WITH INTEGRAL BAFFLE FOR LIQUID
PROOF BARRIER AND/OR LIQUID ABSORPTION**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to protective masks worn to screen and protect from air-borne and liquid-borne contamination.

2. Description of Related Art

Surgical masks are widely employed today in a variety of applications. Although such masks were originally utilized to protect patients from viables carried in the materials expelled from the nose and mouth of the wearer, more recently these masks have been designed and used equally to protect the wearer from air-borne and liquid-borne infectious materials, especially with the growing concern over such diseases as HIV, Hepatitis B, and Tuberculosis. The use of surgical masks to shield against the transference of infectious diseases between a patient and health care workers or others has become an important facet in the overall management of many organizations, including in virtually all health care facilities.

Surgical masks are generally composed of a multi-layered arrangement of materials which singly or together provide particle and aerosol filtration and a level of fluid resistance. Examples of such masks are shown in United States Patents 3,985,132 issued October 12, 1976 to Boyce et al.; 4,323,063 issued April 6, 1982, to Fisichella; 4,606,341 issued August 29, 1986, to Hubbard et al.; and 4,688,566 issued August 25, 1987, to Boyce. Unfortunately, standard surgical masks provide limited liquid resistance and are able to filter only larger aerosol droplets of over 1 micron in size.

A number of masks have been created to address some of these concerns. For instance, laser plume surgical masks have been developed which incorporate filtration media that can filter a high percentage of sub-micron sized particulate matter. These masks are said to protect health care workers from the smoke plume created when lasers or high speed tools are used during surgery.

Similarly, a number of liquid resistant masks have been developed to help limit the effect of "strike through" of body fluids from the patient from reaching the membranes of the nose and mouth of the mask wearer. "Strike through" is defined as the passage of liquid through the layers of the surgical mask from the outside of the mask to the inside.

In their simplest forms, liquid resistant masks are treated with a liquid repellant material, such as fluoroaliphatic resins, which increases the liquid resistance of the fabric. A more advanced system employs an embedded barrier, such as a perforated polyethylene sheet, to aid in avoiding liquid absorption. One such device is disclosed in United States Patent 4,920,960 issued May 1, 1990, to Hubbard et al.

Although such devices are easy to use, regrettably they provide only minimal protection from liquid absorption. In use, liquids can and do pass through these masks. While dry, unused, masks offer the greatest liquid resistance, liquid resistance is steadily reduced as the mask is worn and contaminated with condensed breath, sweat, body oils, saliva, and other fluids.

As the number and/or density of the liquid resistant layers are increased, the liquid resistance is increased both when dry and during wear. Unfortunately, increasing the density of the layers or increasing the number of layers increases the airflow resistance, causing the mask to be harder to breathe through.

An additive problem of decreased moisture vapor transmission is also encountered when additional layers are utilized or the layer density is increased. This causes the mask to retain moisture contained in the sweat and breath of the wearer. Both of these phenomena cause the wearer to experience discomfort, and ultimately the decision by potential wearers not to use the higher protection products. Additionally, with greater resistance to ventilation, there also would appear to be a risk of the vacuum caused by the wearers' inhalation causing undetected amounts of liquid (and contaminants) to pass from the outside of a surgical mask to the inside.

As a result of these drawbacks, a number of other devices have been proposed to place an impenetrable shield between part or all of the wearer's face and the patient. Examples of such devices are

shown in United States Patents 4,796,621 issued January 10, 1989, to Barle et al. (plastic face and eye shield); 4,821,340 issued April 18, 1989, to Johnson (face shield); 4,843,643 issued July 4, 1989, to Parissenti et al. (protective visor); 4,944,294 issued July 31, 1990 to Borek, Jr. (mask with integral eye shield); 4,944,312 issued July 31, 1990, to Smith (face shield); 5,012,805 issued May 7, 1991, to Muckerheide (separate mask barrier); 5,099,525 issued March 31, 1992, to Millauro (full face mask).

Although such shields may function adequately, they suffer from a number of distinct drawbacks. First, since many of these devices employ a separate unit interposed between the wearer and the patient, there is a distinct risk that users will "forget" to wear the shields. This is a common problem when such shields are in any way cumbersome or uncomfortable to wear. Second, many of these shields tend to be overly bulky. This not only decreases the comfort of wearing such shields, but also tends to restrict a wearer's vision and his or her ability to communicate with co-workers. Third, in those instances where the shields form a tight fit with the wearer's face, ventilation may again be unduly restrained. Finally, many of these devices are far too expensive to be made readily disposable, thus increasing the risk of contamination where shields are reused.

Accordingly, it is a primary purpose of the present invention to provide a face mask which protects from liquid strike through, yet is comfortable to wear and provides fully adequate ventilation for the wearer.

It is a further purpose of the present invention to provide such a mask which includes an integral liquid face shield while avoiding the disadvantages of previous shield devices, such as restriction of vision and non-disposability.

These and other purposes of the present invention will become evident from review of the following specification.

SUMMARY OF THE INVENTION

The present invention is a face mask which includes an integral liquid-impenetrable baffle to protect against strike-

through of contaminants. By providing a loose connection between the baffle and filtration layers of the mask, one or more open air spaces are created. This allows the user's breath to pass easily around the baffle while eliminating problematic increased air-flow resistance and reduced moisture vapor transmission inherent in many existing fluid resistant surgical masks.

In one embodiment of the present invention, a baffle of a liquid barrier material is attached across the top of the mask and drapes down to cover the filtration layers of the mask, with an airspace between the baffle and the filtration layers sufficient to allow the passage of the breath of the wearer around the baffle. A wire may be attached across the bottom of the baffle to allow the wearer to shape the baffle to conform to the wearer's face. The resultant curvature of the baffle imparts rigidity to the baffle and reduces the potential of the baffle moving into the field of vision of the wearer.

In another embodiment of the present invention, the baffle is attached to the filtration layer of the mask in several places horizontally across the face of the mask, billowing out therefrom. Resembling bellows, the baffle protrudes away from the mask's filtration layer, forming hollow tubes across the mask face. Inhaled and exhaled air is channeled through the tubes from and to the sides of the mask. The gathering of a surgical mask along the sides of the mask forces the tubes to remain open allowing free passage of the breath.

The mask of the present invention is a permanent liquid barrier which does not decrease in effectiveness during use. Since the baffle is an integral part of the mask structure in the present invention, this invention can be donned by the wearer in the same way as presently utilized surgical masks without extra steps, such as the attachment of a separate shield. The integral baffle is in place whenever the mask is worn, providing protection to the wearer that cannot be compromised by detachment of a shield. The contour of the mask against the face allows for minimal compromise of the field of vision and is fully compatible with other equipment, such as eyeglasses, eyeshields and magnifying units.

DESCRIPTION OF THE DRAWINGS

The operation of the present invention should become apparent from the following description when considered in conjunction with the accompanying drawings, in which:

Figure 1 is a side elevational view of one embodiment of a mask of the present invention shown attached to a wearer's face;

Figure 2 is a plan view of the mask of Figure 1, with its attachment means shown truncated;

Figure 3 is a side elevational view of a second embodiment of a mask of the present invention shown contoured to a person's face;

Figure 4 is a plan view of the mask of Figure 3, with its attachment means shown truncated;

Figure 5 is a side elevational view of a third embodiment of a mask of the present invention shown contoured to a person's face; and

Figure 6 is a plan view of the mask of Figure 5, with its attachment means shown truncated.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is an improved face mask used to cover and protect the face of its wearer. Although the mask of the present invention is particularly applicable for use in a health care environment, where it is not unusual for contaminated liquid to be sprayed in the direction of a health care worker's face, it should be appreciated that the mask of the present invention may also be used in any other environment where liquid strike-through protection is desired.

In the embodiment of the present invention shown in Figures 1 and 2, the mask 10 comprises a filtration layer 12 and a baffle layer 14. In a conventional manner, the filtration layer is worn against a user's face 16, usually covering his or her nose and mouth, and is retained in place via tie strings 18 or similar attachment means. The baffle 14 is designed to stand-off from the user's face 16 and the filtration layer 12 when worn, with an air space 20 established between the baffle 14 and the filtration layer

12.

It is the maintenance of a protective air space 20 which provides the primary liquid strike-through protection of the present invention. Whether or not the baffle layer 14 is even constructed from an liquid impenetrable material, by simply isolating the filtration layer 12 from the baffle 14, liquid striking the baffle 14 cannot reach the filtration layer 12 and thus cannot be absorbed by it.

In the embodiment shown in Figures 1 and 2, the baffle layer 14 comprises a generally rectangular sheet of clear plastic, such as a polyethylene or polypropylene plastic material, having an upper edge 21a, a lower edge 21b, and two side edges 21c, 21d. In this form, the baffle 14 is attached to the filtration layer 12 only along its upper edge 21a to nose bridge 22. When worn in the manner shown, the baffle layer 14 hangs freely down from the nose bridge 22 and inherently forms the necessary air space 20. By causing the baffle 14 to extend below the level of filtration layer 12, a distinct screen is created to shield the wearer from liquid spray and particularly spray originating from in front and below the wearer.

As is often employed today, the nose bridge 22 of this construction includes a malleable seam 24 therein which permits it to be molded to fit snugly the contour of the wear's nose and face. This bridge 22 may be constructed from any suitable material, such as flat aluminum wire.

To aid in maintaining the orientation between the filtration layer 12 and the baffle 14, this embodiment also includes a lower seam 26 attached to the baffle's lower edge 21b which provides additional mass to the baffle 14. A moldable material 28 may also be provided in the baffle's lower seam 26 to allow it to be shaped to any desired orientation. It has been found that by forming the lower seam 26 in the arcuate shape shown in Figure 1, the baffle 14 tends to maintain its proper position through most common movements, even when the wearer needs to lean forward.

In use, the mask 10 of the present invention provides a distinct barrier to liquid sprayed at a wearer's face. In the embodiment of Figures 1 and 2, such a spray of liquid will simply strike the baffle 14 and drip off, with minimal risk of liquid

strike-through or later absorption through the filter media. Moreover, as is explained in more detail below, the mask of the present invention provides unrestricted air flow to the wearer and avoids many of the problems encountered with previous liquid barriers.

Due to the nature of the present invention, it can be straightforwardly combined with virtually any conventional mask construction. For example, the filtration layer may incorporate any applicable style, such as pleated, duck-billed, or cone, and most forms of filtration media. For additional protection, the present invention may also be combined with other liquid-protection technology, such as polypropylene layering in the filtration media, or eyeshield protection. Likewise, the mask 10 of the present invention can be provided with any form of attachment means, such as tie strings 18 or elastic loops.

A variation on this basic mask is shown in the embodiment of Figures 3 and 4. In this embodiment, multiple baffles 30, 32 are attached to filtration layer 34. Each of the baffles 30, 32 are attached to the filtration layer 34 along an upper edge 36a, 38a, respectively. To aid in retaining these baffles 30, 32 in place, they may be provided with the lower seam illustrated in Figures 1 and 2, and/or they can be anchored along side edges, 36b, 36c, and 38b, 38c.

It has been found that by anchoring the multiple baffles 30, 32 along their upper and side edges in the manner shown, when the mask is worn, each of the baffles will form a protruded orientation away from the filtration layer 34, with each maintaining an open air space 40, 42. As is shown, this embodiment contemplates a significant degree of overlap between or among multiple baffles so as to provide adequate protection when extended into an installed position on the wearer's face.

A further improvement contemplated by the present invention is to provide an absorbent layer on the baffle which will prevent liquid from dripping off onto a work surface. In the embodiment of Figures 3 and 4, such an absorbent layer 44 comprises a polyester, rayon, cellulosic non-woven fabric, or similar material bonded to a substrate of impermeable material, such as polyethylene.

Since it is the maintenance of the air spaces which provides

the primary protection of the filtration layer in the present invention, although not preferred, it should be understood that the baffles may be constructed from merely absorbent material alone. In such a case, any spray of liquid would merely be absorbed by the baffle and retained away from the filtration layer during use. Suitable materials for use under these circumstances include rayon, polyester, and cellulosic non-woven fabric.

Another variation of the present invention is shown in Figures 5 and 6. In this embodiment, the baffle 46 comprises a sheet of material anchored to a filtration layer 48 at its upper edge 50 and lower edge 52. By leaving sufficient slack in the material, the material forms a bellow 54, with its side edges 56, 58 billowing away from the filtration layer 48. This provides the desired air space 60 while permitting the free-flow of air around the side edges 56, 58.

Although the present invention may function adequately in this respect with a single bellow 54, it is preferred to form this baffle with a series of multiple bellows in the manner shown in Figures 5 and 6. The multiple bellows can be formed by attaching to the filtration layer 48 a series of separate rectangular sheets arranged in parallel, with each sheet forming a bellow away from the filtration layer. Alternatively, the multiple bellows can be formed as one or more larger rectangular sheets anchored at their upper and lower edges with an additional attachment (e.g. one or more parallel welds to the filtration layer) intermediate its upper and lower edges to form the bellowed configuration.

The multiple bellowed embodiment of the present invention is considered particularly desirable since the baffle remains in place even during vigorous head movement. Moreover, with the sides of the bellows open to the free flow of air, this embodiment has proven to be quite comfortable to wear and breathe through. For best performance in both of these regards, the apex of each bellow 54 (i.e. that portion of the bellow which is furthest from the filtration layer when the bellow is fully extended) should be at least 1 to 2 cms from the filtration layer 48.

It should be appreciated that many of the attributes discussed above may be modified or combined to address particular applications. For instance, for most surgical applications,

regardless of which embodiment is employed, it is considered desirable to include both a liquid impenetrable layer and a liquid absorbent layer as the baffle. This construction serves both to assure complete splash-through protection and to minimize liquid run-off from the mask which might contaminate a surgical site.

A further improvement which can be provided is to include an anti-microbial agent in the baffle. This acts to protect the wearer and also helps to limit contamination from run-off from the baffle. Suitable agents include quaternary ammonium compounds.

Unlike previously available face shields and so-called liquid impermeable surgical masks, the mask of the present invention in no way stifles the ability of the wearer to breathe. The substantial open air space or spaces provided with each of the embodiments of the present invention allows for the free movement of respiration to and from the exterior of the mask's filtration layer.

Further, since the mask is a simple one-piece unit, the barrier protection is provided each time it is worn. This avoids the all-too-common problem of wearers "forgetting" to apply it.

More importantly, the barrier provided by the present invention is quite comfortable and is in no way unpleasant to wear. Not only is breathing through a mask of the present invention far easier than with other liquid-resistant masks, but it in no way obscures the user's vision or communication, as is often a problem with various face shield designs. Thus, the present invention is considered far more desirable to use than any other liquid-resistant barrier now available.

While particular embodiments of the present invention have been illustrated and described herein, the present invention should not be limited to such illustrations and descriptions. It should be apparent that changes and modifications may be incorporated and embodied as part of the present invention within the scope of the following claims.

The invention claimed is:

1 1. A mask for covering at least a portion of a wearer's face
2 to filter the wearer's respiration and to protect against liquid
3 strike-through contamination, which comprises:

4 a filtration layer, including an interior and exterior
5 side thereto;

6 means to attach the filtration layer to the wearer's
7 face;

8 a baffle layer attached to the filtration layer so as to
9 shield the exterior of the filtration layer when worn;

10 wherein, when worn, the baffle layer assumes an
11 orientation away from the filtration layer so as to form an open
12 air space therebetween of sufficient dimensions to permit the free
13 flow of respiration to and from the exterior of the filtration
14 layer.

1 2. The mask of claim 1 wherein the baffle layer comprises
2 at least one sheet of liquid barrier material having
3 upper and lower edges;

4 wherein the liquid repellant material is anchored to the
5 filtration layer only along its upper edge.

1 3. The mask of claim 2 wherein the liquid barrier material
2 includes a malleable seam along its lower edge, permitting the
3 lower edge of the material to be shaped.

1 4. The mask of claim 3 wherein the malleable seam includes a
2 wire formed within the lower edge of the fluid repellant material.

1 5. The mask of claim 2 wherein multiple liquid barrier
2 materials are attached to the filtration layer.

1 6. The mask of claim 1 wherein the baffle layer includes an
2 anti-microbial agent.

1 7. The mask of claim 2 wherein an absorbent material is
2 affixed to the liquid barrier material to assist in controlling
3 liquid run-off from the baffle.

1 8. The mask of claim 1 wherein the baffle layer comprises
2 at least one sheet of generally rectangular liquid
3 barrier material having upper, lower, and side edges;

4 wherein the liquid barrier material is anchored to the
5 filtration layer along its upper and lower edges and with
6 sufficient slack therebetween so as to cause the side edges of the

7 material to form a bellow protruding out from the filtration layer
8 when worn.

1 9. The mask of claim 8 wherein the baffle layer comprises
2 multiple sheets of liquid barrier material, each sheet being
3 anchored to the filtration layer so as to cause its side edges to
4 form a bellow protruding out from the filtration layer when worn.

1 10. The mask of claim 9 wherein at an apex of each bellow,
2 each of the side edges extends at least 1 cm from the filtration
3 layer.

1 11. The mask of claim 8 wherein the liquid barrier material
2 is anchored to the filtration layer intermediate its upper and
3 lower edges so as to cause the liquid barrier material to form
4 multiple bellows protruding out from the filtration layer.

1 12. The mask of claim 11 wherein at an apex of each bellow,
2 each of the side edges extends at least 1 cm from the filtration
3 layer.

1 13. The mask of claim 1 wherein the baffle layer comprises
2 at least one sheet of liquid barrier material having
3 upper, lower and side edges;

4 wherein the liquid barrier material is anchored to the
5 filtration layer along only its upper and side edges, the lower
6 edge protruding out from the filtration layer when worn.

1 14. The mask of claim 13 wherein multiple sheets of liquid
2 barrier material are provided, each sheet mounted to the filtration
3 layer along only its upper and side edges, with the lower edges
4 protruding out from the filtration layer when worn.

1 15. A face mask which comprises
2 a filtration layer and an integral baffle;
3 wherein open air space is provided between the baffle and
4 the filtration layer when worn so as both to separate liquids
5 impacting the baffle from absorption by the filtration layer, and
6 to provide free flow of a wearer's respiration around the baffle.

1 16. The mask of claim 15 wherein the baffle comprises an
2 absorbent layer of material.

1 17. The mask of claim 15 wherein the baffle comprises a
2 liquid impermeable barrier material.

1 18. The mask of claim 17 wherein the baffle comprises
2 at least one sheet having upper, lower, and side edges;

3 wherein the sheet is anchored to the filtration layer
4 along its upper edge.

1 19. The mask of claim 18 wherein the material is anchored to
2 the filtration layer along its upper and lower edges and with
3 sufficient slack therebetween so as to cause the side edges of the
4 material to form a bellow protruding out from the filtration layer
5 when worn.

1 20. The mask of claim 18 wherein the sheet includes a
2 malleable seam along its lower edge, permitting the lower edge to
3 be shaped.

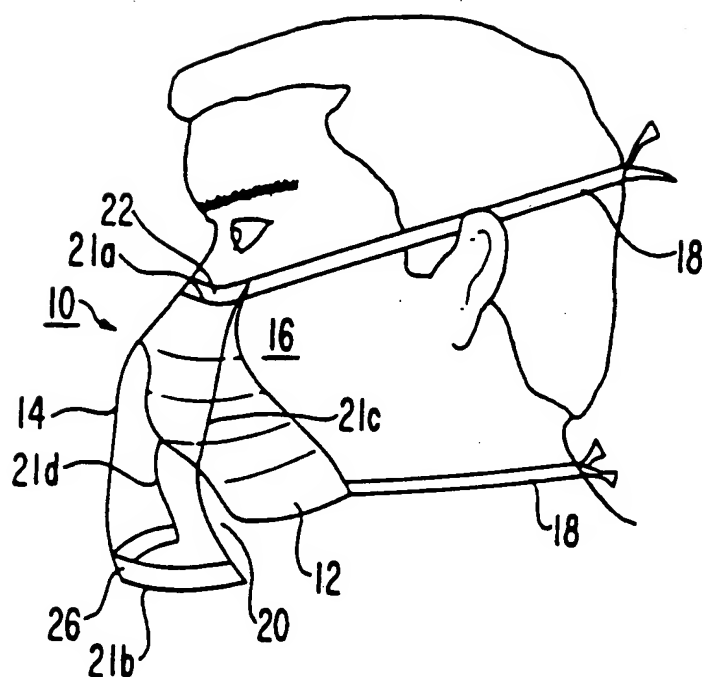
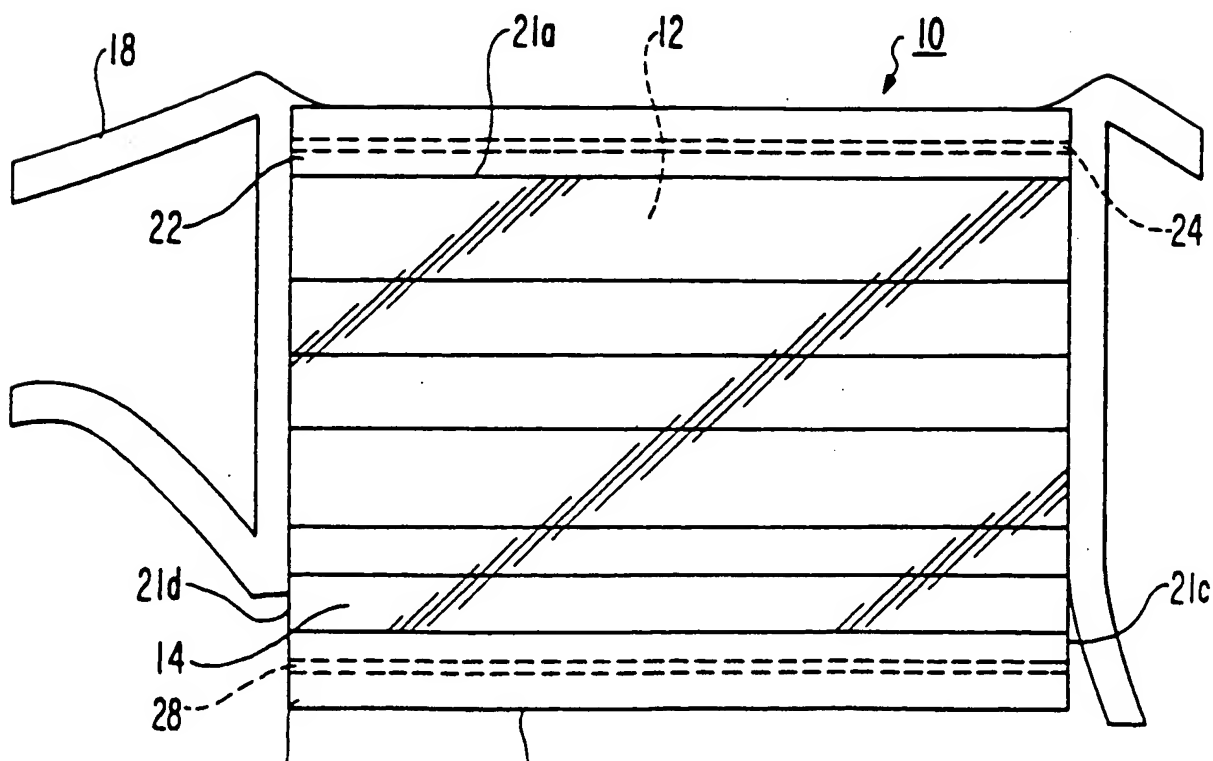
FIG. 1**FIG. 2**

FIG. 3

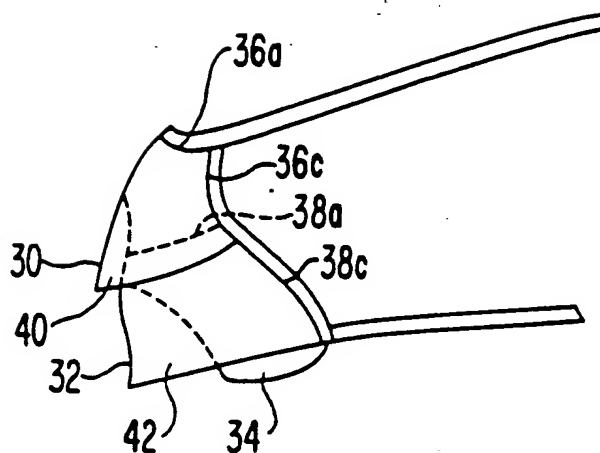


FIG. 4

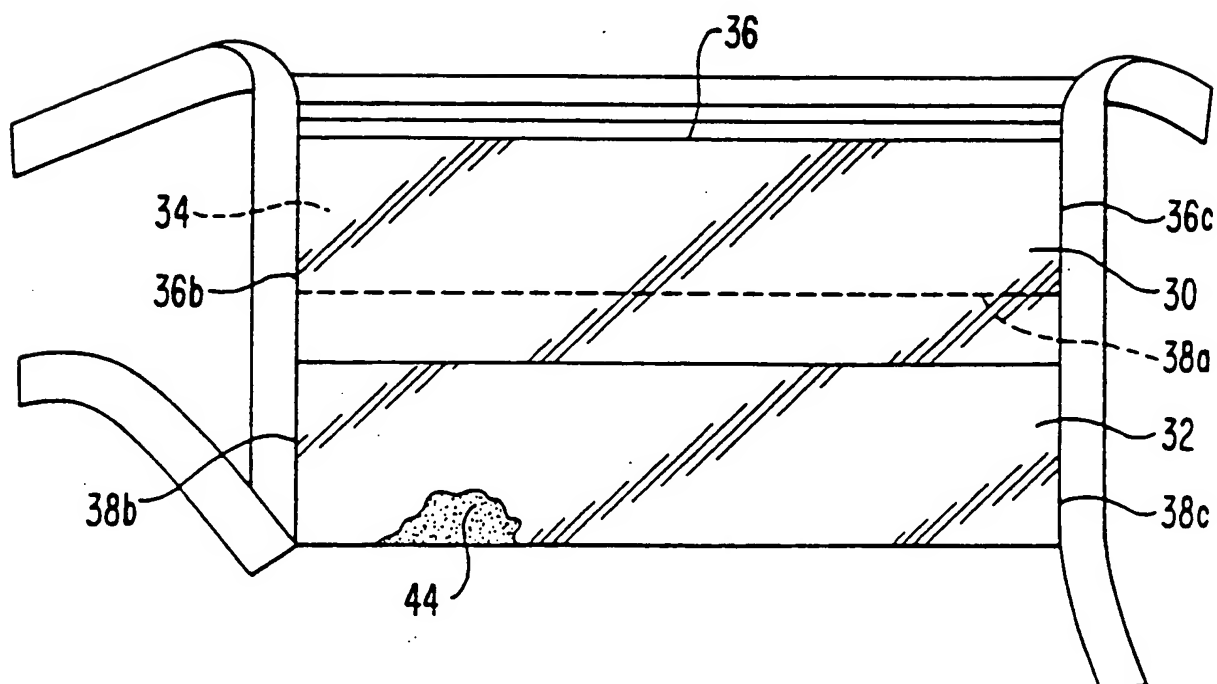


FIG. 5

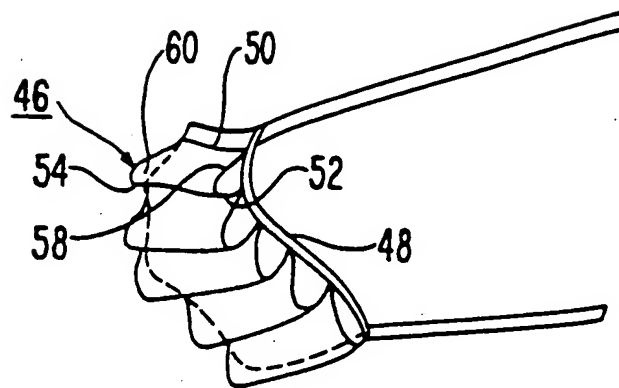
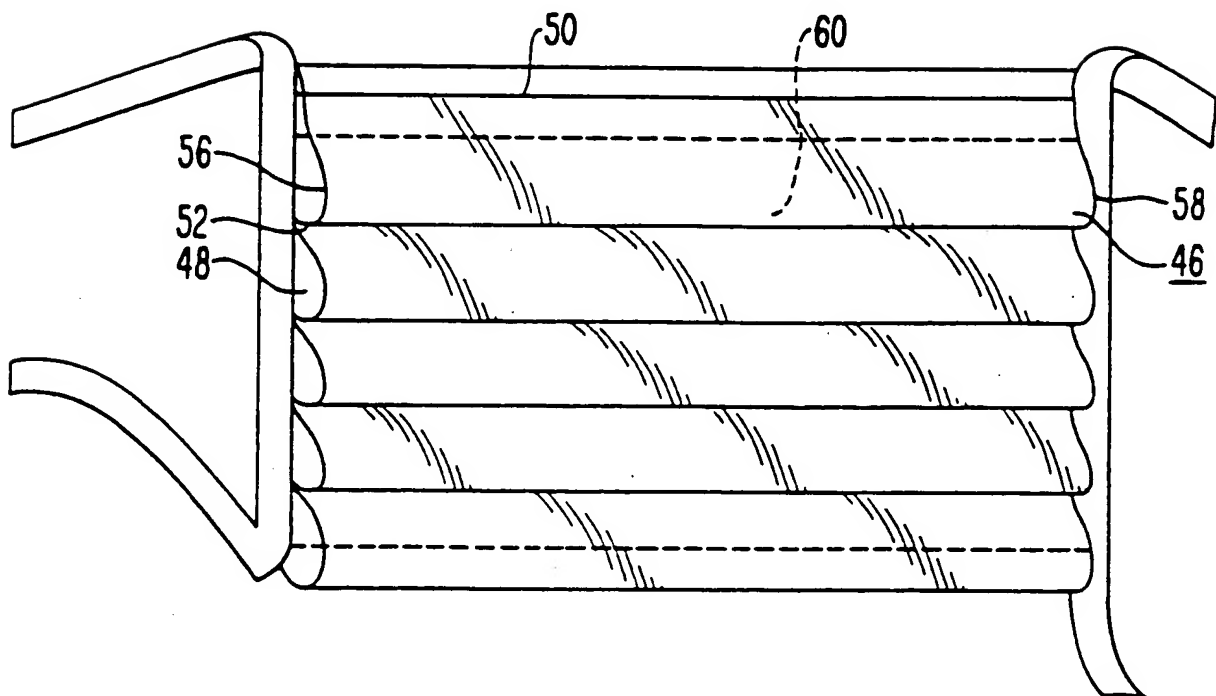


FIG. 6



INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 93/03478

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A41D13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A41D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BE,A,463 397 (J. BEDE) 1 July 1946	1,8, 13-15
Y	see page 5, column 16 - page 6; figure 5 ---	2,17,18
Y	US,A,4 821 340 (A.E. JOHNSON) 18 April 1989 cited in the application see the whole document ---	2,17,18
Y	US,A,4 944 312 (B.S. SMITH) 31 July 1990 cited in the application see the whole document ---	1-5,7-9, 15-20
Y	US,A,4 920 960 (V.M. HUBBARD & AL) 1 May 1990 cited in the application ---	1-5,7-9, 15-20
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Date of the actual completion of the international search

9 November 1993

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

VANMOL, M

INTERNATIONAL SEARCH REPORT

Inter. Appl. No.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 93/03478

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US-A-4821340	18-04-89	NONE	
US-A-4944312	31-07-90	NONE	
US-A-4920960	01-05-90	US-A- 5020533	04-06-91
		US-A- 4969457	13-11-90
		US-A- 5150703	29-09-92
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		CA-A- 2014053	07-10-90
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